



# Guidance for Managing Intellectual Assets in Patient and Public Involvement (PPI) Contexts

Version 1.1. March 2026

**Outline and purpose of the document:** These *Guidelines for IP and Data in Patient & Public Involvement (PPI)* are part of the IMPAC3T-IP 'Co-creation / PPI' tool-kit. They are designed to help mixed teams (researchers, clinicians, charities, patient groups, industry and public bodies) navigate copyright, data, and licensing in PPI projects. The guide provides a practical and accessible framework to understand, manage, and leverage intellectual assets (IA) and intellectual property rights (IPR) that arise from co-created outputs from PPI (e.g., stories, images, toolkits, questionnaires, datasets, software, names/branding). By clarifying ownership, recognition and benefit-sharing, access and licensing choices, confidentiality and data governance, the tool supports ethical, equitable, and sustainable use of PPI results, enabling teams to publish, share, and scale impact with confidence.

**Target readership:** This document is intended for project leads and coordinators working with PPI, individual researchers and clinicians, Technology Transfer Offices (TTO), research support units, charities and Non-Governmental Organisations (NGO) partners, community representatives, and SMEs involved in creating, disseminating, or managing PPI outputs (e.g. training materials, toolkits, surveys and clinical outcome assessments, audio-visual content, datasets and software).

**Level:** The document assumes a basic understanding of PPI practice but no prior expertise in IPR or data licensing. Teams new to IPR or data management should consult institutional experts or legal professionals to ensure compliance with applicable laws, ethics approvals, and policies.

**Focus:** To provide clear guidance on contribution and copyright ownership, recognition and benefit-sharing, access rights and licensing (e.g. Creative Commons for content, open-source options for software, data-sharing and data-processing agreements), confidential information, and consent language that links ethics and IPR. It addresses typical PPI challenges such as multiple contributors, community IP, translations/derivatives, open access vs. sustainability, GDPR-aligned data roles, and equitable access for non-profit and public interest use.

**Scope:** To explain key legal and procedural concepts in a practical, step-by-step way, with checklists and decision points for planning, ethics submission, publication, and downstream licensing. The guidelines recognize that many users are unfamiliar with IPR and data frameworks and aim to reduce friction while protecting contributors, enabling reuse, and supporting impact pathways.

**Disclaimer:** This guide reflects the authors' best understanding of issues that may arise in managing IP, data, and disclosure in PPI projects at the time of writing. As these fields continue to evolve, it should be used only as general guidance and not as a substitute for professional legal, IP, or data-protection advice. The authors, IMPAC3T-IP, and project partners accept no responsibility for outcomes arising from its use.

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## Acronyms

COA	Clinical Outcome Assessment
DPIA	Data Protection Impact Assessment
EDPB	European Data Protection Board
FTO	Freedom-to-Operate
GDPR	General Data Protection Regulation
IA	Intellectual Assets
IP	Intellectual Property
IPO	Intellectual Property Office
IPR	Intellectual Property Rights
KT	Knowledge Transfer
MoU	Memorandum of Understanding
NDA	Non-Disclosure Agreement
NGO	Non-Governmental Organisations
ORCID	Open Researcher & Contributor ID
OSI	Open Source Initiative
PPI	Public & Patient Involvement
RPO	Research Performing Organisation
SME	Small and Medium Enterprises
TTO	Technology Transfer Offices

# 1. Introduction & Purpose

Patient and Public Involvement (PPI) projects aimed at healthcare improvements bring together different participants and stakeholders including universities, hospitals, large and small enterprises, charity organizations, start-ups, patient advocates, carers and individual citizens to co-design new diagnostics, devices and services. Motivation, resources, expectation and contribution of the participants may differ, necessitating a process that is very different from commercial product and service development. Success in PPI projects is more usually concerned with lived experience and measurable benefits for patients and communities rather than profit maximisation. Nevertheless, realizing benefits from the results and resilient long-term sustainability of PPI programmes require clear allocation and management of intellectual assets (IA) and intellectual property (IP).

Contributions in a PPI setting – ideas, data, stories, prototypes, code – often come from partners with very different legal experience and resources. This is one reason why IA and IP management questions might be postponed or ignored, especially in the early stages of a project. However, if ownership, attribution and reward are not agreed early, it can result in lost impact, broken trust, absence of resilience or stalled commercialization. There are many guides for universities and companies describing what steps should be taken while working with patients and communities, but often they only list ethics-based procedures to be followed and do not address the issues to be considered around IA and IP contributions.

This guide explains not only how to manage IA and IP in PPI projects, but also why each step matters. It helps teams understand the underlying rationale behind good IP practice, so they can make informed decisions in diverse and evolving contexts. It offers a phased roadmap and practical tips to support fair recognition and reward, while addressing ethical considerations, power imbalances, transparency, and the long-term sustainability of innovation, so that participants are not exploited by more experienced commercial or institutional partners.

The guide will be useful for all participants of a PPI innovation process, especially individuals, researchers, organizations with insufficient or no legal support. It will be relevant to university departments responsible for engaged and citizen research and municipal government or funding organizations whose work is related to the organization of projects aimed at solving social issues. Representatives of Knowledge Transfer (KT) and TT offices can use this guide to assist them when interacting with the above-mentioned entities during structuring of licensing deals or other transactions related to the commercialization of intellectual assets produced by PPI projects.

The principles of managing IP in co-creation projects, as addressed across the Impac3t-IP Toolbox<sup>1</sup>, generally apply; results have the characteristics of co-created projects, such as challenges in attribution. In the case of a PPI project, the contributions of participants may vary greatly, but the collaborative effort toward a common goal remains, and each participant, including patients, carers, representatives of charities and communities, contributes to the project through their personal experience, organizational expertise, or training.

All checklists and questions are specifically designed for the Project Lead, i.e. the person designated responsible for project success and development. However, all material may be considered useful to any PPI participant.

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<sup>1</sup> <https://www.impac3tip.eu/toolbox/>

## 1.1. How to use this Guide

In this guide, a “PPI project” means any research, innovation or service-improvement activity that is carried out with or by patients, service users, carers or members of the public based on their lived experience, rather than for or about them. Typical examples include co-design and co-creation of digital health tools and ‘know-your-health’ applications, joint development of care pathways, or evaluation of existing services in partnership with community groups. In these Guidelines, the “context” covers several phases:

- preparation of co-creation R&D and innovation projects, including drafting funding applications;
- project set-up and day-to-day management, including ethics and data-governance processes;
- downstream use, licensing and commercialisation of outputs such as tools, apps, datasets or training materials.

You can therefore use this guide both when planning a new project and when structuring licensing deals or other transactions for results that come out of PPI work. The guide covers the full life-cycle of a PPI project. You may dip into sections as needed:

- When preparing a funding proposal or new project: start with Sections 1 and 3 and the quick-start timeline.
- When defining roles, agreements and governance: use Section 2 (key concepts, roles and the decision matrix).
- When planning recognition, benefit-sharing and licensing: consult Section 4.
- When handling patient or citizen data and consent: use Section 5 together with your institutional GDPR and data management policies.
- When reviewing a running project or preparing for scale-up: revisit the checklists in Sections 3, 4 and the Key Takeaways.

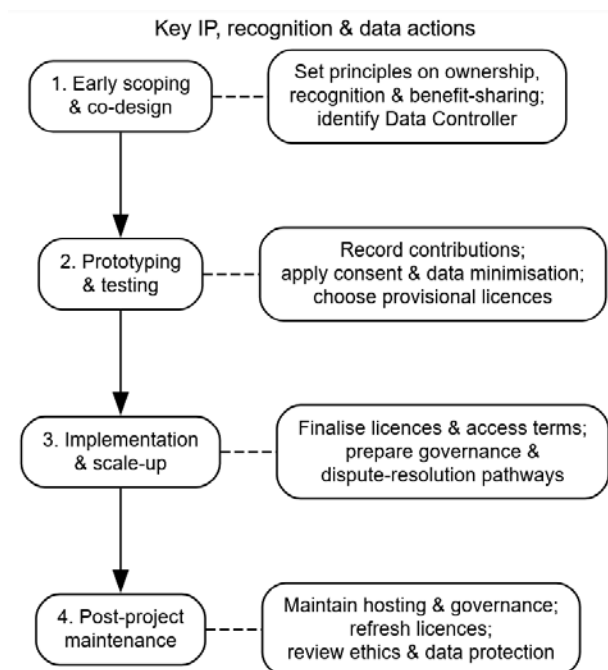
Examples, questions and checklists are primarily aimed at Project Leads, but any team member can use them to prepare for discussions with partners, funders, legal advisers or data-protection officers.

## 1.2. Where IA and Ethics feature in a PPI Project

In a typical PPI project, concerns about IA, ethics and data protection arise at various key stages. Sections 2–5 of this guide explore questions and checklists to use at each of these points.

- Early scoping and co-design - agreeing aims, partners, expected outputs and first ideas on ownership, recognition and consent.
- Prototyping and testing - creating tools, apps, measures or materials together; combining contributions from individual participants and organizations.
- Implementation and scale-up – sharing results with wider communities, rolling out tools or services, and negotiating licenses or access terms.

- Post-project maintenance – keeping the outputs up to date, paying for hosting or support, and deciding how far to open or restrict reuse.



### 1.3. Why think about IA in PPI?

If we ignore it...	If we manage it...
<ul style="list-style-type: none"> <li>• Patients', citizens' and other participants' ideas or data may be reused without credit or consent.</li> <li>• Unclear ownership blocks investors and regulators ("Who can authorize this app?").</li> <li>• Later disputes erode trust and can end projects.</li> </ul>	<ul style="list-style-type: none"> <li>• All contributors know how they will be recognized, rewarded or paid.</li> <li>• Licences and permissions are in place before trials, accelerating ethics and regulatory approval.</li> <li>• Funders and companies see a clear route to scale-up and real-world use.</li> </ul>

#### Key points

1. Definitions: It is important to distinguish clearly between IA, IP, and IPR. IA encompass any result of intellectual activity, including ideas, know-how, and creative works, regardless of their legal status. IP refers to the subset of IA that qualify for legal protection, such as inventions, literary works, or distinctive signs. IPR, in turn, are the legal instruments – patents, copyrights, trademarks, design rights, and trade secrets – through which IP is formally protected and enforced. In other words, IP is the protectable output of intellectual activity, while IPRs are the rights that secure it; having IP does not automatically mean holding IPR.

2. **Scope:** In PPI, when referring to IPRs, we include not only patents but also copyrights, design rights, and related protections that may apply to outputs such as photos, videos, stories, survey data, software code, or even a project name. Each of these outputs may constitute IP and may carry specific IPR that require permission before they can be shared, used, or published.
3. **Fair recognition:** Patients, carers and other individuals often contribute unique lived experiences. They might have social or private motivations to participate, and might not understand the concept of project resilience and the necessity to secure and maintain the project, which could result in divisions within the team or failure of the project. A simple royalty share, voucher, public credit, or co-authorship shows respect and keeps parties engaged.
4. **Trust & ethics:** Clear IP rules sit alongside GDPR and ethics approvals. Telling people upfront how their input may be commercialized can help to avoid a feeling of being exploited.
5. **Speed to impact:** Hospitals, start-ups, and funders move faster when they know who owns what and which licence applies. Early clarity can prevent months of renegotiation at the launch stage.
6. **Long-term sustainability:** An agreed IP and licensing plan may allow a scenario where a tool remains free for charities yet is paid for by commercial insurers, enabling tool maintenance and update without the need to source new grants.
7. **Remember:** good IA management in PPI isn't about "locking up" knowledge; it's about making use possible - safely, fairly, and at scale.

## 2. Key Concepts & Roles

The concepts and roles in this section apply throughout a PPI project, not only when signing licences. They are relevant when:

- designing a project and preparing a funding application;
- running workshops and collecting contributions;
- drafting agreements and consent forms;
- publishing results or negotiating downstream licensing.

Keeping the same language for IP, data and roles across these phases makes it easier for partners and contributors to understand what is happening and to give informed consent.

## 2.1. Know Essential Terms

Term	What it means in a PPI project.
Attribution & Reward	Practical ways to acknowledge and, where relevant, compensate contributors (credits, co-authorship, royalties, vouchers, travel grants, equity).
Confidentiality / Non-Disclosure Agreement (NDA)	Information shared under duty of confidence (for example draft business models, unpublished results). An NDA sets out who may see it and for what purpose.
Copyright	Automatic right that protects text, images, videos, code, and training materials created by contributors.
Data Ownership / Control	Legal responsibility for personal or health data - covers consent, storage, and secondary use, in line with GDPR and national rules. Often held by a hospital, university or public body as Data Controller.
Intellectual asset / intangible assets	Any result of intellectual and creative activity that might have commercial or societal value.
Intellectual property (IP)	The subset of intangible assets that qualify for legal protection (for example an invention, a distinctive logo, a software, database or an original training manual).
Intellectual property rights (IPR)	The legal rights that protect IP, such as patents, copyrights, trademarks, design rights and trade secrets. Having IP does not automatically mean holding IPR - the rights may belong to an employer, funder, publisher, etc.
Licence	Permission stating <i>who</i> may use the IP, for <i>what</i> purpose, and under <i>which</i> conditions.
Patent	Time-limited monopoly on a novel technical solution (e.g., sensor, algorithm); needs formal filing and approval.
Trade Secret / Know-how	Valuable recipe, dataset, or parameter set kept confidential instead of patented. Protection depends on keeping access limited and controlled.

Refer to more detailed explanation can be found on WIPO<sup>2</sup> “What is Intellectual Property?”.

Remember: if in doubt, treat any creative or technical output as protected IP and seek written permission before reuse.

<sup>2</sup> <https://www.wipo.int/en/web/about-ip>

## 2.2. Know Typical Roles and Responsibilities

Role	Main Responsibilities
Project Lead / PL	Ensures an IP exploitation plan exists, balancing open science with commercial goals, responsible for the final decision in signing off rights or licences. Typically a research performing organization (RPO) but may also be a commercial entity or Governmental Agency.
IP / Knowledge Exchange / Technology Transfer Officer	Single point of contact for all IP matters. Logs invention disclosures, checks patentability, files and maintains patents, drafts / negotiates licences and data-sharing clauses, keeps template agreements up to date, monitors royalty flows, ensures GDPR and ethics compliance and briefs team and funders on risks and next steps. If not a direct participant in the project, they can nevertheless provide templates, draft agreements, advise on risk and assist in checking compliance.
Patient, Carer, or other Individual Contributor	Provides lived-experience insights or data, agrees to contribution licence or signs off the rights, while receiving attribution/reward.
Clinician / Healthcare Partner	Shares clinical data or protocols; checks compliance with ethics and GDPR.
Academic Researcher	Generates results, software or publications; flags potential new IP early to the IP officer.
Industry Partner / SME	May fund development; needs freedom-to-operate for commercialization.
Data Controller	Holds legal responsibility for personal data; issues data-processing agreements.
Funder / Sponsor	Sets IP conditions (e.g. open access); may require revenue-sharing or impact metrics.

## 2.3. Know Who Decides What

In co-creation projects involving diverse stakeholders, IP related decisions (including licensing decisions) may require sign-off from multiple parties. It is important to clarify who is authorized to approve each decision. Absence of agreement concerning responsibility for the process could result in chaos, implementation delays or failure and loss of funding.

Some documents, for example a NDA, are rigid and allow little flexibility. However, for documents dealing with IA created in the project, different levels of responsibility may be defined for participants. This means that from the outset all project participants must agree on the process for IP decision making and approval. The project leader should consider the development of a specific document (an IA Plan or Policy) and include specific clauses into project agreements.

Document / Action	Parties	Typical project phase
Confidentiality (NDA)	Project Lead + all data-sharing parties	Early scoping; before exchanging non-public information.
Participant Contribution Agreement	Project Lead + Patient/Carer	Before or at the start of co-creation activities.
Data-processing Agreement	Data Controller + Processor	When appointing an external processor (e.g. survey platform, cloud provider).
Patent filing	Inventor(s) + IP Officer + Institution	After identifying a potentially patentable invention.
Licensing	Licensor representative + Licensee	When providing ongoing access or commercial rights to project outputs.

Typical authorization roles in case are:

- **On behalf of the licensor** (the party granting rights): Academic lead, Project Lead or manager, Knowledge Exchange or Technology Transfer Officer, or organization legal team. One or more of these individuals may approve, depending on institutional policies.
- **On behalf of the licensee** (the party receiving them): The individual requesting the licence, their line manager, general manager of the organization or an authorized legal representative, depending on the nature and purpose of the licence.
- Licensing decisions should be consistent with the IP Plan and funding conditions, and should reflect any prior agreements with contributors, including patients or carers where relevant.

## 3. Get Ahead – Advice for Early Stages

Getting IA right in PPI is mostly about *starting early*. Use the checklist below before funding applications are submitted, and repeat it at the kick-off meeting. Find time to return to these questions on a regular basis as the understanding of the project and intellectual assets may evolve over time (depending on the project duration this could be monthly or biannually).

Refer to the “Decision Tool for Societal Benefit from Co-created Results Rights Management” in the IMPAC3T-IP co-creation toolkit. It is a practical, short, “yes/no” flowchart to help PPI projects follow best-practice in managing expected IPR.

#	Answer Readiness Question	Why it matters
1	<b>Have we listed the likely “outputs”?</b> (data, software, stories, designs, names)	No list → no ownership clarity later.
2	<b>Who are the IA owners on day 1?</b> (university, hospital, charity, individuals)	Prevents surprises when filing patents or releasing code.
3	<b>What will contributors get in return?</b> (credit, royalties, vouchers, co-authorship)	Sets expectations, sustains trust and engagement. If royalty is expected, understand who will be administrating them.
4	<b>Is there a simple contribution agreement template ready?</b>	Saves weeks of legal drafting when recruitment begins.
5	<b>Have we mapped personal data flows and consent?</b>	Links GDPR/ethics to downstream licensing; avoids re-consenting later.
6	<b>Is there a budget line for IP costs?</b> (legal review, rights maintenance, licensing costs)	Grants rarely cover late-stage IP fees unless ring-fenced early.
7	<b>Is there a named IP/KE/TT officer on the project team?</b>	Provides a single point of contact for queries and filings.
8	<b>Are there decision rules for open vs. restricted release?</b>	Balances public benefit with commercial freedom-to-operate (FTO).
9	<b>Is there a mitigation plan if a key partner withdraws?</b>	Ensures intellectual assets survive staff turnover or site closures.
10	<b>Which of the above questions is it necessary to revisit?</b> How and when?	Guarantees that any unpredicted issues and circumstances changes would be considered.

### 3.1. Quick-start Timeline

Time spent on “readiness drills” can save months of renegotiation and keep your PPI project on the fast track to real-world impact. In the initiation, include:

- **Proposal stage** – draft a one-page *IP & Data Plan* covering the ten questions above.
- **Funding awarded / ethics prep** – circulate the plan for sign-off; embed IP clauses in consent forms and Memorandums of Understanding (MoU).

- **Kick-off week** – 30-minute “IP briefing” with all partners and patient reps; agree where documents are stored; what kind of regular meetings are required and when.
- **Month 3 review** – confirm that contribution agreements are signed and (if applicable) all patentability screens are complete.

## 4. Considering Community IP & Benefit-Sharing

Patient and public contributors often supply ideas, personal stories, photos, data, code or designs that the project cannot otherwise generate. When these pieces are merged into a single output – an app, a dataset, a training video – they form *community intellectual property* (Community IP<sup>3</sup>). Managing Community IP maintains trust, and demonstrates to stakeholders that the project is ethical and sustainable.

### 4.1. Who “owns” Community IP?

Source	Default rule	Usual adjustment in PPI projects
Individuals (patients, carers)	Holds copyright in anything they create.	Sign a short <b>Contribution Agreement</b> that keeps ownership with them <i>but</i> grants the project a royalty-free licence to use, adapt and, where agreed, commercialise.
Partner charities / clinics	Provides background IP	Draft a <b>Collaboration Agreement or MoU</b> : partner licenses background IP into the project, receives share of any project income.
Project team (university, industry)	Follows IP Policy	Confirm in the <b>Consortium Agreement</b> or any other Project Agreement that Community IP will be co-owned or pooled.

#### 4.1.1. Choose a Benefit-Sharing scheme

Choose one (or mix several) and document the choice early.

Option	How it works	Typical when...
Remunerated participation	Participant (patient, expert) gets remuneration for the contribution made; all rights are signed off to other participants	Participant doesn't play any role in co-creation, his/her contribution is short in terms of time and they have no possibility to spend time on the project development and prefer recognition over money. However, many participants are

<sup>3</sup> <https://prism.sustainability-directory.com/term/community-intellectual-property/>

		ready to contribute without any remuneration.
Acknowledgement only	Name in credits, ORCID <sup>4</sup> listing, certificate, etc.	Contribution is small, or participants prefer recognition over money.
Voucher / Travel grant	Fixed-value voucher for training, events or devices.	Budget is limited; reward must be non-cash.
Revenue share	Royalty split (e.g. 2–5%) or micro-payments e.g. per app download.	Output will generate sales or licence fees.
Equity or token	Small share in a spin-out or social-enterprise token.	In a high-growth digital health project. Note that many hospitals have no legal structures to hold equity.
“Pay it forward” fund	Portion of income set aside for future patient-led ideas.	Community requests collective rather than personal gain.

#### 4.1.2. Plan Licensing Strategy and Pathways

Licensing must balance openness, recognition, control, and need for impact to serve all participants from patients to commercial partners. NIHR provide framing questions<sup>5</sup> to develop your plan:

1. **Why license this asset?**
  - Widen access?
  - Support community adoption?
  - Generate revenue for future research?
2. **What outcomes matter most?**  
Patient benefit, academic credit, market impact, policy influence, etc.
3. **Are stakeholders aligned?**  
Research team, TTO, patients, clinicians, funders, industry partners.
4. **What are the risks?**  
IP leakage, misuse, reputational harm, litigation, licence incompatibility.

Answers guide approach to trade-offs and constraints, such as:

- **IP protection versus Openness**  
Even when you decide the project results should be available on a royalty-free basis licensing helps to ensure the results are used in a planned / proper way. It also helps to get feedback for further project development.

<sup>4</sup> <https://orcid.org/>

<sup>5</sup> <https://www.nihr.ac.uk/get-involved/public-involvement>

- **Social Impact** versus **Commercial Return**  
Mind the necessity to maintain the results after the project is finished. You may need a permanent cash flow to make the results sustainable and resilient.
- **Funder Mandates**, e.g. open-access requirements
- **Resourcing**, including TTO and legal support.

### 4.1.3. Example Licensing Pathways

Pathway	Examples of Usage
<b>Open Licenses</b>	CC BY-NC 4.0 <sup>6</sup> for educational resources; attribution required. Open-source licences <sup>7</sup> (OSI-approved) for software code, scripts, data-analysis notebooks
<b>Dual licensing</b>	CC BY <sup>8</sup> for charities alongside commercial licence; free for non-commercial use, allowing non-profits to access assets freely while industry scales commercially
<b>Collective marks<sup>9</sup></b>	Trademark to protecting project name/logo, while allow approved patient groups to use it
<b>Full commercial licence</b>	When a commercial company is involved, may be the only option

For pharma, biotech and medtech industries, licensing decisions often interact with clinical-trial and regulatory pathways. For example, a co-created symptom-tracking app or outcome measure may:

- be available under a free or low-cost license for academic or non-commercial studies;
- require a paid license or service agreement when used in sponsored clinical trials;
- need to meet EU medical device software guidance and national rules if classified as a medical device.

When planning such projects, involve your TTO and regulatory experts early to avoid blocking data reuse or trial approvals later.

## 4.2. Practical Tips

1. Explain benefit-sharing in plain language during onboarding; avoid legal jargon.
2. Put license statements *on the materials themselves* (slide footer, data-dictionary header).
3. Revisit the agreement yearly - people's views on recognition or reward can change.

<sup>6</sup> <https://creativecommons.org/licenses/by-nc/4.0/deed.en>

<sup>7</sup> <https://opensource.org/licenses>

<sup>8</sup> <https://creativecommons.org/licenses/by/4.0/deed.en>

<sup>9</sup> <https://www.wipo.int/collective-marks/en/>

4. Keep a simple ledger of how revenue is allocated; transparency prevents later disputes.

#### **While working with commercial partners and large organisations:**

1. Map decision-makers early – find out who in the university, hospital or company can sign NDAs, contribution agreements and licenses (for example the TTO, legal office, or procurement team).
2. Prepare before approaching – use this guide to draft a short IP/Data summary (one page) so busy offices can respond faster.
3. Be realistic about incentives – some TTOs focus on high-revenue patents. Emphasize non-financial impact (equity, policy influence, patient outcomes) as well as realistic incomes.
4. Support “jobbing academics” and front-line professionals – provide them with template emails or checklists so they can request the right support even if the central office seems uninterested.
5. Include funders where relevant – some funders have specific IP and access requirements. Share early drafts of your IP/Data plan with them where possible.

### 4.3. Dealing with disagreements and disputes

Even in well-run PPI projects, disagreements may arise about recognition, access to data or licensing choices. A simple “what-if” pathway helps to protect trust and avoid escalation:

1. **Spot issues early** – encourage team members and contributors to raise concerns as soon as they feel uneasy about IP, data or recognition.
2. **Talk first, in plain language** – hold a short meeting focused on understanding the problem and restating the agreed principles (fairness, transparency, equity).
3. **Check the paperwork** – review contribution agreements, consent forms and the IP/Data plan to see what was agreed and whether it still fits the situation.
4. **Use internal escalation** – if needed, involve an institutional contact (for example a mediator, ombudsman, PPI lead or TTO) who is not directly involved in the project.
5. **Agree next steps in writing** – document any changes or compromises in a short addendum signed by the affected parties.
6. **Have a last-resort option** – contracts may name a neutral mediator or arbitration service to use if informal steps fail.

Building this pathway into your initial agreements can prevent stalled projects, legal threats and loss of trust.

### 4.4. Examples of Good and Poor Practice

#### **Good practice – shared recognition and clear rewards**

A university, hospital and patient group co-create a self-management workbook. Early in the project they agree that patients keep copyright in their stories but grant the project a license to use them. The hospital hosts the PDF under a CC BY-NC licence;

patient contributors are named as co-authors and receive travel-cost vouchers for workshops. When a charity wants to translate the workbook, the original group is consulted and the license is extended.

### **Poor practice – “old hands” push for one-sided rights**

A commercial partner offers to fund an app development if it receives all IP and data rights. The project team, unfamiliar with licensing, accepts a draft contract without independent advice. Later, contributors discover that their stories are used in a paid product with no recognition or benefit for them. Trust collapses and recruitment stops.

### **How to avoid exploitation**

To avoid exploitation by more savvy and aggressive partners who are old hands and happy to push for their own commercial gain:

- budget for at least one independent legal or TTO review of key IP and data clauses;
- avoid signing “all rights” clauses without clear reasons and safeguards;
- ensure patients and public contributors understand in simple terms how any commercial partner may benefit;
- consider caps or minimum standards for recognition and benefit-sharing across all partners.

## **5. Examine Data Privacy & Ethics**

In a PPI project, personal data means any information that can identify a person, directly or indirectly. Examples include:

- name, email address, phone number or social-media handle;
- age, postcode, rare disease or detailed health history;
- photos, videos or audio recordings where a person can be recognized;
- an ID code that can be linked back to a person through a separate key;
- combinations of data (for example diagnosis + small clinic + rare language) that make someone identifiable.

Under GDPR, the Data Controller (usually a hospital, university or public body) decides why and how personal data are processed and is responsible for keeping them safe and lawful. The project must follow the Controller’s policies and templates and not invent parallel rules.

Patient-centred projects may handle sensitive health facts, photos and personal stories. A few simple rules keep everyone safe, and the project compliant.

Step	What to do	Why it matters	When
1. Collect only what you need	Ask for the minimum data that meets the research goal.	Less data = less risk if something leaks.	At project design and whenever you add a new questionnaire or tool.
2. Explain in plain words	Give a one-page consent sheet: what we collect, why, who sees it, how long we keep it.	People cannot give real consent if they do not understand.	Before recruitment and whenever the project purpose changes.
3. Name a Data Controller	One partner (often the hospital or university) is officially in charge of storage and access.	Required by GDPR <sup>10</sup> ; makes lines of responsibility clear.	At proposal or contract stage; confirm again at ethics submission.
4. Secure storage	Use encrypted drives or a trusted cloud that meets ISO 27001/NHS standards <sup>11</sup> . No USB sticks.	Protects against hacks and accidental loss.	Before any personal data are collected; review when storage systems or providers change.
5. Anonymize or pseudonymize early	Replace names with codes before files are shared outside the core team.	Even if the file travels, it reveals little.	Before sharing data beyond the core team and whenever a new dataset or export is created.
6. Ethics + DPIA check	Submit the project to an ethics committee and complete a Data Protection Impact Assessment <sup>12</sup> .	Shows funders that risks were weighed and reduced.	Before starting data collection and again if there are major protocol or data-use changes.
7. Right to withdraw	Tell participants they can pull their data out at any time without penalty. Have a quick removal process.	Builds trust; also a legal right under GDPR.	At consent stage; remind at key contact points (e.g. follow-up visits or major project updates).
8. Controlled sharing	Open data = <i>only</i> after re-identification risk is near zero; otherwise share under a data-use agreement.	Balances open science with privacy duties.	Before each planned data release or external data share.
9. Keep an audit trail	Log who accessed the dataset, when and why; store the log for at least 5 years.	Provides evidence if something goes wrong.	From the first data access onwards; update the log every time data are viewed,

<sup>10</sup> <https://gdpr-info.eu/>

<sup>11</sup> <https://digital.nhs.uk/cyber-and-data-security/guidance-and-assurance/data-security-and-protection-toolkit-assessment-guides/guide-9---it-protection/frameworks-that-can-help>

<sup>12</sup> <https://www.autoriteitpersoonsgegevens.nl/en/themes/basic-gdpr/gdpr-in-practice/data-protection-impact-assessment-dpia>

			copied or shared.
10. Review annually	Check consent forms, storage and access lists once a year and after any data breach.	Ensures safeguards stay up to date.	Once a year and after any significant change or data breach.

Also consider:

Link consent language to IP and data reuse: consent forms should not only describe what data will be collected and for how long, but also:

- whether participants' stories, images or quotes may be used in training, publications or digital tools;
- whether any commercial partners may later be involved;
- how contributors will be recognized and, where relevant, rewarded;
- whether participants can choose between different levels of sharing.

Make sure the consent text matches the project's IP and licensing plan and is consistent with European Data Protection Board<sup>13</sup> (EDPB) or national data-protection guidance.

A warning – when PPI outputs become medical devices: some apparently simple tools (for example symptom checkers or BMI calculators inside an app) may fall under medical device or similar regulation in your jurisdiction. This can trigger extra approval steps, labelling and post-market duties. When planning digital tools that influence diagnosis or treatment, check early with your institutional regulatory or clinical governance team whether your output could be classified as a medical device. This avoids surprises after you have already invested in development.

What if there is a data breach? A data breach means that personal data are lost, destroyed, changed or accessed by someone who was not allowed to see them (for example lost laptop, wrong email recipient, hacked cloud account).

If a breach happens, do not try to "fix it quietly". A transparent and fast response protects participants and shows funders and regulators that the project takes its duties seriously.:

1. check and follow your organization's incident procedure immediately;
2. inform the Data Controller and your data-protection officer;
3. record what happened, which data were involved and which safeguards were in place;
4. check whether the breach must be reported<sup>14</sup> to the national data-protection authority or EDPB, and to affected participants, within the specified timelines.

<sup>13</sup> [https://www.edpb.europa.eu/edpb\\_en](https://www.edpb.europa.eu/edpb_en)

<sup>14</sup> [https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-92022-personal-data-breach-notification-under\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-92022-personal-data-breach-notification-under_en)

## 6. Summary and Key Takeaways

### Summary of Recommendations by Phase

PPI phase	Main questions	Key actions and tools
<b>Preparation and proposal</b>	Who are the partners and contributors? What outputs do we expect? Who owns what on day 1?	Use Section 1 (Introduction), Section 2 (Key Concepts & Roles) and Section 3 (Readiness checklist and quick-start timeline). Draft a one-page IP & Data plan and identify the Data Controller and IP/TTO contact.
<b>Co-creation and project delivery</b>	How do we recognise and reward contributions? How do we keep data safe and lawful?	Use Section 4 (Community IP & Benefit-Sharing) and Section 5 (Data Privacy & Ethics). Put contribution agreements and consent forms in place, and schedule regular reviews of ownership, licences and privacy.
<b>Scale-up and post-project</b>	How do we licence and govern the outputs for long-term use? How do we handle disagreements?	Use Sections 4.1–4.3 (licensing pathways, practical tips and dispute-resolution) and the Useful Links. Agree benefit-sharing, document licence terms, and decide how hosting, updates and governance will be financed after the initial grant.

## Takeaways

	Details	What to do
<b>Start thinking of IA on day 1</b>	A one-page IP & Data plan drafted at kick-off prevents most later delays.	<b>Book a 30-minute IP briefing</b> with your Knowledge Exchange Officer / Technology Transfer Officer / legal representative.
<b>Write it down</b>	Even a light-touch template signed by all contributors is better than verbal promises.	<b>List expected outputs</b> (datasets, code, stories) and draft ownership lines in a shared document.  <b>Select a contribution-agreement template</b> , adapt, if necessary, but in the absence of professional legal support try to minimize adoption to two clauses max. to prevent losing or blurring of key concepts. Circulate for signatures.
<b>Understand what people expect and share fairly</b>	Have an agreement about what people expect. For instance, build in simple, transparent benefit-sharing-credit, vouchers, revenue splits-before launch.  Consider partners opinion and find consensus	<b>Add one slide on benefit-sharing</b> (how recognition or payments will work) to the project induction deck.
<b>Keep data safe</b>	Minimal collection, encrypted storage, clear consent.	
<b>Review, don't park.</b>	Revisit ownership, licenses and privacy regularly. Depending on the project and its length it can be made every three months, once a year or whenever partners change.	<b>Schedule an annual IA &amp; data review</b> in everyone's calendar for the whole project duration.

## Annex I. Useful Links

1. **“How to Involve and Engage Patients in Digital Health-Tech Innovation – An Evidence-Based Guide”** (Health Innovation Network, 2022) – a practical four-step framework with a dedicated section on data ownership and IP rights:

[https://www.healthinnovationyh.org.uk/wp-content/uploads/2022/07/ppie\\_guide.pdf](https://www.healthinnovationyh.org.uk/wp-content/uploads/2022/07/ppie_guide.pdf)

<https://thehealthinnovationnetwork.co.uk/national-publications/how-to-involve-and-engage-patients-in-digital-health-tech-innovation-an-evidence-based-guide/>

2. **NIHR – Intellectual Property & Commercialisation Guidance** – explains how UK public-funded health projects should identify, own and licence IP generated with patient input:

<https://www.nihr.ac.uk/research-funding/application-support/guidance/domestic-programmes-outline-application-guidance>

3. **UKRI EPSRC “Health-Technologies Impact & Translation Toolkit: Intellectual Property”** – checklist of IP issues to cover when applying for translational health grants:

<https://www.ukri.org/councils/epsrc/guidance-for-applicants/what-to-include-in-your-proposal/health-technologies-impact-and-translation-toolkit/showing-value-in-healthcare-technologies/intellectual-property/>

4. **“First Evidence-Based Guide for PPIE in Health-Tech Innovation”** – news overview summarising the above guide’s key findings on data privacy, inclusivity and IP:

<https://thehealthinnovationnetwork.co.uk/news/first-evidence-based-guide-for-patient-and-public-involvement-and-engagement-in-health-tech-innovation-launched/>

5. **HSE Ireland Guide No. 8: Patient & Public Involvement in Research** – concise PDF with sections on consent, data sharing and copyright when working with service users:

<https://hseresearch.ie/wp-content/uploads/2021/12/Guide-no-8-Patient-and-Public-Involvement-in-HSE-Research.pdf>

6. **Lambert Toolkit for University–Business Collaboration Agreements** (UK IPO) – model contracts widely used to clarify background/foreground IP and revenue-sharing in joint projects:

<https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit>

7. **“Patient and Public Involvement in Research: A Review of Resources”** (Arumugam A. et al., 2023) – academic review that maps current PPI guidance, including material on licensing participant-generated outputs:

<https://pmc.ncbi.nlm.nih.gov/articles/PMC9996937/>

8. **NIHR Domestic Programmes – Application Guidance (IP Section)** – outlines what funders expect in the “IP & Data” part of a health-research proposal:

<https://www.nihr.ac.uk/domestic-programmes-funding-guidance-full-applications>

9. **European Data Protection Board (EDPB)** - Guidelines, Recommendations, Best Practices:

[https://www.edpb.europa.eu/our-work-tools/general-guidance/guidelines-recommendations-best-practices\\_en](https://www.edpb.europa.eu/our-work-tools/general-guidance/guidelines-recommendations-best-practices_en)

## Annex II. Sample Workshop Formats

### Workshop 1 – “Mapping contributions and expectations” (60–90 minutes)

- *Aim:* help all participants see who brings which assets (stories, data, expertise) and what they expect in return.
- *Steps:*
  - Short introduction to IP, IPR and Community IP (10 minutes).
  - 1. Small-group exercise: list contributions and hoped-for benefits on sticky notes or a shared board (30 minutes).
  - 2. Plenary: cluster notes into themes (recognition, income, open access, privacy) and identify any tensions (30 minutes).
  - 3. Agree next steps: who will draft the IP/Data plan and by when (10 minutes).

### Workshop 2 – “Using scenarios to discuss licensing and access” (60 minutes)

- *Aim:* test different licensing options with patient and public contributors in a safe way.
- *Steps:*
  1. Present 2–3 short fictional scenarios (e.g. open licence vs paid licence vs mixed model).
  2. Ask groups to discuss what feels fair or unfair and why.
  3. Capture key points on a flipchart: conditions for acceptable commercial use, minimum recognition, red lines.
  4. Use these inputs to refine the project’s licensing strategy.

These formats can be adapted to online or hybrid meetings using simple tools such as slides and shared documents.

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